



THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

The School of Medicine
Department of Obstetrics & Gynecology
Division of Reproductive Endocrinology and Fertility
Area Code 919 - 966-5283

The University of North Carolina at Chapel Hill
CB# 7570, Old Clinic Building
Chapel Hill, NC 27599-7570

November 5, 1999

Paula S. McKeever
Center for **Biologics** Evaluation and Research (HFM-17)
Food and Drug Administration
1401 Rockville Pike, Suite 200 N
Rockville, Maryland 20852-1448

RE: Docket #97N-484S

Dear Ms. McKeever,

I enjoyed speaking with you earlier this week after reviewing the proposed rule regarding suitability determination for donors of human cellular and tissue based products. My primary concern regards CMV status of sperm donors. Presently our Sperm Bank at the University of North Carolina at Chapel Hill tests our donor's serum for IgG CMV antibody. The donors are retested at 6 months. If the donor turns out to be positive for IgG then his sperm is used only to inseminate CMV IgG positive women. My concern would be in the future, incorporating the suggested changes, as to whether we would still be able to use a sperm donor who tested positive for CMV in a CMV positive recipient.

A second concern centers on oocyte donation. I am concerned that a 6 month quarantine time for the embryos would not only decrease considerably the success of egg donation but would require that donors return at 6 months for retesting prior to performing an embryo recipient transfer. This would become a logistic nightmare and is different from sperm donation where gametes rather zygotes are cryopreserved.

I look forward to a final ruling from the Department of Health and Human Services.

Sincerely,

William R. Meyer, MD
Assistant Professor
Division of Reproductive Endocrinology & Fertility

WRM/rs

cc: Dr. Marc Fritz
OB/GYN
CB #7570

Dr. Stan Beyler
OB/GYN
CB #7570

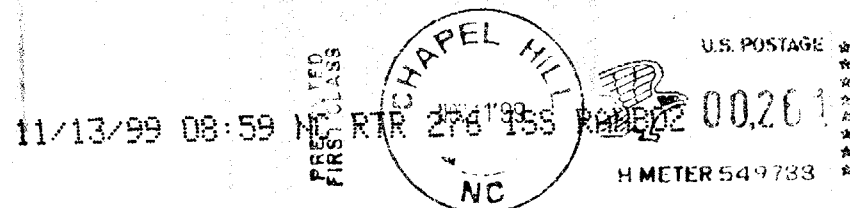
97N-484S

C11

5730 59 NOV 26



The School of Medicine
Department of Obstetrics & Gynecology
Division of Reproductive Endocrinology
and Fertility
The University of North Carolina at Chapel Hill
CB# 7570, Old Clinic Bldg.
Chapel Hill, N.C. 27599-7570



PAULA S. MCKEEVER
CTR FOR BIOL EVALUATION & RES (HEM-17)
FOOD AND DRUG ADMINISTRATION
1401 ROCKVILLE PIKE SUITE 200 N
ROCKVILLE MD 20852-1448

